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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,389	11/18/2003	Peter Elsbach	28297/32248C	6372
4743	7590	12/29/2005	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			MINNIFIELD, NITA M	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,389	Applicant(s) ELSBACH ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) <u>4 pgs.</u> | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed September 26, 2005 is acknowledged and has been entered. Claims 1-9 have been canceled. Claim 10 has been amended. Claims 10-15 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The disclosure is objected to because of the following informalities: the ATCC address is incorrect. Appropriate correction is required. The current address of the ATCC is as follows:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209
4. Claim 11 is objected to because of the following informalities: there is not period at the end of sentence. Appropriate correction is required.
5. Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "the amino acid sequence set forth in

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Figure 5". A review of the drawings filed November 18, 2003 include Figure 5A, 5B, 5C and 5D. Which one of these figures, 5A, 5B, 5C or 5D does Applicant intend in the recitation of "Figure 5" in independent claim 10? What part or portion of Figure 5A, 5B, 5C or 5D is the biologically active recombinant NH₂- terminal fragment of BPI protein? Claims 13 and 15 are vague and indefinite in the recitation of the amino acid sequence set forth on line 3 of claim 13. It is not clear what sequence in the specification the claimed sequence corresponds to. The amino acid sequence in the claims contains 19 amino acids. SEQ ID NO: 3 and 4 contain 20 amino acids. Is the claimed amino acid sequence supposed to be the same as the holoprotein and 25 kD fragment as set forth in Table 2 of the specification? Claims 12 and 15 are indefinite because they contain the abbreviations "SDS-PAGE". Full terminology should be in each instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Correction is required.

6. The terminal disclaimer filed on September 26, 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6287811 has been reviewed and is accepted. The terminal disclaimer has been recorded.

7. Claims 10-15 are rejected under the judicially created doctrine of double patenting over claims 1 and 2 of U.S. Patent No. 5,641,874 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: "Isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein" and "A eukaryotic host cell stably transformed or transfected with isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein".

This rejection is maintained for the reasons of record. The terminal disclaimer filed on September 26, 2005 with regard to 5641874 is improper since these rejections are statutory type double patenting rejections. The filing of a terminal disclaimer cannot overcome a double patenting rejection based on 35 U.S.C. 101. Applicants should cancel and/or amend the claims to overcome this rejection.

8. Claims 10-15 are rejected under the judicially created doctrine of double patenting over claims 1-4, 6 and 7 of U.S. Patent No. 5,198,541 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: "Isolated DNA encoding a NH2-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein" and "A eukaryotic host cell stably transformed or transfected with

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isolated DNA encoding a NH₂-terminal polypeptide bactericidal/permeability-increasing fragment of bactericidal/permeability protein which is up to about half the size of said protein”, “Isolated DNA sequence encoding human bactericidal/permeability increasing protein fragment comprising from about residue 1 to about residue 210”.

This rejection is maintained for the reasons of record. The terminal disclaimer filed on September 26, 2005 with regard to 5198541 is improper since these rejections are statutory type double patenting rejections. The filing of a terminal disclaimer cannot overcome a double patenting rejection based on 35 U.S.C. 101. Applicants should cancel and/or amend the claims to overcome this rejection.

9. No claims are allowed.


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
December 19, 2005